OCT 1 1 2002

GE Imatron

General Electric Company
389 Oyster Point Boulevard
South San Francisco, CA 94080
800 367-6545, 650 583-9964
gemedical.com

A GE Medical Systems Company

K022794

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter:

Kerry A. Spear
Regulatory and Compliance Manager, GE Imatron
TEL: 650-742-8801 FAX: 650-827-7790
Summary prepared: 19 July 2002

PRODUCT IDENTIFICATION

Name: e-Speed Electron Beam Tomography (EBT) Scanner System

Classification Name: Angiographic X-ray System
Computed Tomography X-ray System

Manufacturer: GE Imatron
389 Oyster Point Boulevard
South San Francisco, CA 94080

Distributor: Same as Manufacturer

Marketed Devices: The e-Speed EBT Scanner System is of comparable type and is substantially equivalent to currently marketed EBT and Computed Tomography X-ray Systems that comply with the same or equivalent standards and have the same intended uses.

DEVICE DESCRIPTION

The e-Speed EBT Scanner System ("e-Speed") is composed of a Gantry/Front End Assembly, Rear Electrical/Mechanical Assembly with Electron Source, Patient Table, Operator Console, Computer, HV Power Supply and Power Conditioning and Distribution System, water chiller, and associated accessories.

Materials: Materials and construction are equivalent to the C150XP EBT Scanner System (K001550) and are compliant with UL2601-1, IEC 60601-1, and 21CFR Subchapter J.

Design: The system is designed to be an angiographic X-ray system, and a whole body CT scanner utilizing electron beam technology, a modernized beam control system and redesigned x-ray data acquisition system, a higher power HV supply, an operator console, and the capability to scan at 0.050 sec as the primary mode of operation.

Indications for Use:

The intended use of the proposed GE Imatron e-Speed EBT Scanner System remains unchanged from the intended uses of prior predicate Imatron devices and other scanners. The e-Speed is designed – as are all predicate devices – to produce cross sectional images of the entire human anatomy.

Specifically, the e-Speed is intended:

1. to permit radiologic visualization of the heart, blood vessels, or lymphatic system, during or after injection of a contrast medium;

2. to function as a diagnostic x-ray system to produce two and three dimensional images of the heart, blood vessels, or lymphatic system from a volume of computer reconstructed cross-sectional images from x-ray transmission data from the same axial plane taken at different angles;

3. to permit the data from certain three dimensional images to also be presented in time-sequenced or cine fashion;

4. to permit the data from three dimensional images to be viewed from a point of view moving inside the tissue, called "fly-through" mode for colons, blood vessels, or airways;

5. to be used for clinical situations requiring determination of specific quantitative information, such as the determination of calcium or other materials in bone, tumors, or organs;

6. to be used by the physician as an aid in the diagnosis of lung pathology;

7. for real-time motion studies, vascular and tissue blood flow analysis, and full three-dimensional volume imaging.

The e-Speed will make use of previously cleared workstation software products and software applications.

Finally, such system is intended to be used in a manner consistent with those devices already classified and set forth in 21 CFR Sections 892.1600 and 892.1750.

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Comparison with Predicate:

It is the opinion of GE Imatron that the e-Speed EBT Scanner System is of a type and substantially equivalent to currently marketed angiographic and whole body X-ray computed tomography systems with respect to design, material composition, energy source, and radiation characteristics. It will comply with the X-ray safety requirements of 21CFR 1020.30, 1020.31, and 1020.33, as well as the safety requirements of UL2601-1, IEC 60601-1 and applicable collateral and particular standards.

Adverse Effects on Health:

Potential electrical, mechanical, and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements;
- Adherence to industry and international standards (UL/CSA and IEC).

CONCLUSIONS

The e-Speed EBT Scanner System does not result in any new potential safety risks and performs as well as or better than devices currently on the market. GE Imatron considers the e-Speed EBT Scanner System to be equivalent to other marketed devices with the same indications for use and meeting similar standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 11 2002

General Electric Imatron
% Mr. Nishith Desai
Primary Third Party Reviewer
TÜV Rheinland of North America, Inc.
12 Commerce Road
NEWTOWN CT 06470

Re: K022794
Trade/Device Name: e-speed Electron Beam Tomography (EBT) Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 JAK
Dated: September 27, 2002
Received: September 27, 2002

Dear Mr. Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): ___K022794____

Device Name: e-Speed EBT Scanner System

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3. to permit the data from certain three dimensional images to also be presented in time-sequenced or cine fashion;

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022794

Prescription Use ✓ - OR - Over-The-Counter Use _____
(Per 21 CFR 801.109)

4. to permit the data from three dimensional images to be viewed from a point of view moving inside the tissue, called "fly-through" mode for colons, blood vessels, or airways;

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